

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Edwin Lephart et al.)	
)	Examiner: Zarek, Paul E.
Serial No. 10/533,045)	
)	Group Art Unit No. 4161
Filing Date: October 20, 2005)	
)	Confirmation No. 6027
For: USE OF EQUOL FOR TREATING)	
ANDROGEN MEDIATED)	
DISEASES)	

DECLARATION OF EDWIN DOUGLAS LEPHART
UNDER 37 C.F.R. § 1.131

I, Edwin Douglas Lephart, Ph.D., declare that:

1. I am one of the named inventors of the subject matter of the above-identified patent application ("the '045 application").
2. I received a B.A. in Psychology in 1979 and an M.S. in Experimental Psychology in 1982 from Brigham Young University, Provo, Utah. I graduated from The University of Texas Southern Medical Center, Dallas, Texas in 1989 with a Ph.D. in Physiology (Molecular Biology). After receiving my Ph.D., I was a Research Fellow in the Department of Obstetrics and Gynecology at the Green Center for Reproductive Biology Sciences from 1989 to 1993 and in 1993 I was a Research Fellow in the Department of Internal Medicine, Division of Endocrinology and Metabolism at the University of Texas Southwestern Medical Center at Dallas, Texas. I also held an

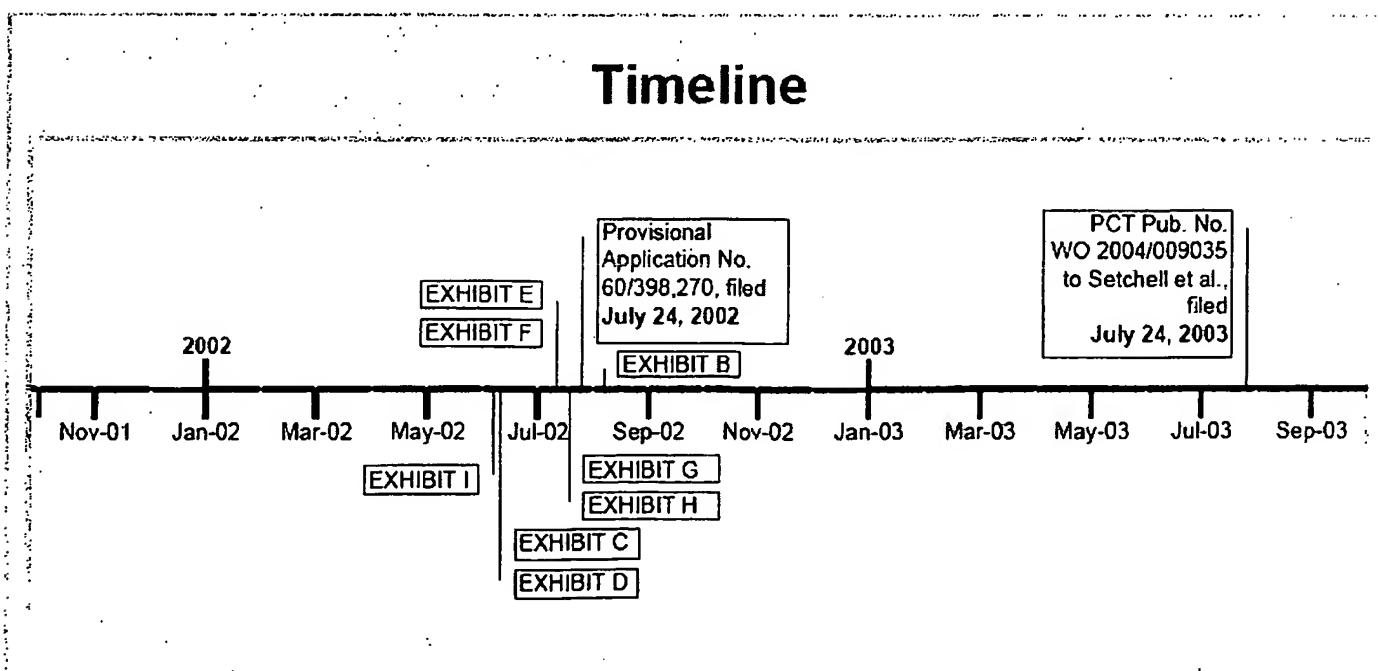
Assistant Professor position in the Department of Psychiatry at the University of Texas Southwestern Medical Center at Dallas, Texas in 1994. From 1994 to 1997, I was an Assistant Professor in the Department of Zoology, Cellular Biology Division at the Brigham Young University. Since October 1997, I have held an Associate Professor and since 2003 a Professor position in the Department of Physiology, Developmental Biology and Neuroscience at the Brigham Young University. My curriculum vitae is attached hereto as Exhibit A.

3. While at Brigham Young University, I have devoted a major portion of my scientific work towards studying phytoestrogens, including equol and their characteristics and applications for treatment of various conditions including, for example, skin and brain disorders and diseases as well as prostate diseases and conditions. I have published my findings in 18 scientific papers and numerous abstracts. I have also presented my work at numerous seminars and conferences throughout the world. A listing of my publications, abstracts, seminars, and conferences is contained in my curriculum vitae (Exhibit A).
4. I have read the Office Action mailed September 10, 2008 in the '045 application. I have reviewed and am familiar with U.S. Patent Publication No. 2004/0235758 to Setchell and Cole (hereinafter "Setchell and Cole") that the Examiner relies upon in this Office Action.

5. Regarding the Examiner's rejection, I understand that the Examiner asserted that my invention, as claimed in the '045 application, is anticipated by the Setchell and Cole reference. I understand that the Examiner cited numerous teachings of Setchell and Cole in paragraph 16 of the Office action to support his assertion.
6. Importantly, the teachings identified by the Examiner in paragraph 16 of the Office action were invented by me and the remaining inventors named in the '045 application prior to the filing date of the Setchell and Cole reference, which is July 24, 2003 and, further, the teachings were invented by me and the remaining inventors named in the instant application prior to the filing of the priority document to Setchell and Cole, Provisional Application No. 60/398,270 (hereinafter "the '270 priority application"), which was filed July 24, 2002.
7. The purpose of this declaration is:
 - a. to provide the Examiner with evidence that I and the remaining inventors named in the '045 application, Trent D. Lund at Colorado State University, Kenneth David Reginald Setchell from Cincinnati Children's Medical Center, and Robert J. Handa at Colorado State University, collaborated with the group of Setchell and Cole prior to the filing date of the Setchell and Cole reference and prior to the filing date of the '270 priority application;

- b. to provide the Examiner with evidence that the subject matter of the '045 application was discussed between myself and the remaining inventors named in the '045 application prior to the filing date of the Setchell and Cole reference and prior to the filing date of the '270 priority application; and
- c. more importantly, to provide the Examiner with evidence that I and the remaining inventors named in the '045 application knew and understood the importance of equol, including its S- and R-enantiomers, and their potential use for prostate health, and specifically, in treating and/or ameliorating benign prostatic hyperplasia and prostate cancer, prior to the filing date of Setchell and Cole and prior to the filing date of '270 priority application.

8. For convenience of the Examiner, I am providing a timeline of the Exhibits B-I discussed hereinbelow.



9. The '045 application and the Setchell and Cole reference cited by the Examiner have one inventor in common, namely Kenneth David Reginald Setchell. Kenneth David Reginald Setchell, myself, and the remaining inventors named in the '045 application collaborated prior to the filing date of the Setchell and Cole reference, as well as, prior to the filing date of the '270 priority application. During our collaboration we discovered that the racemic and non-racemic mixtures of R- and S-enantiomers of equol can be used for treatment of conditions of the prostate.
10. Exhibit B is a copy of the Colorado State University Disclosure of Invention dated August 6, 2002. This Disclosure of Invention lists four inventors, Robert Handa, Trent Lund, Kenneth Setchell and myself, all of whom are also the inventors named in the '045 application. At page 1 of the Disclosure of Invention, the date of May 2001 is listed as the date of the first disclosure of the invention described therein to others and the date of first sketch or drawing relating to the invention described therein. The Disclosure of Invention also provides the date of May 30, 2001 as the date of the first written record of the invention described in the Disclosure of Invention. Thus, Exhibit B is evidence of an ongoing collaboration between the inventors named in the '045 application, at least from May 2001. All these dates precede the filing date of the Setchell and Cole reference and that of the '270 priority application.

11. Exhibit B also provides evidence that the inventors of the '045 application knew about equol and its potential applications for treating or ameliorating conditions of the prostate as claimed in the '045 application, prior to the filing date of the Setchell and Cole reference and the '270 priority application. Specifically, at page 2 of Exhibit B, under "Brief Summary of the Invention," inventors disclose that equol binds directly to the androgen, 5 α -Dihydrotestosterone (5 α -DHT). Under "Practical and Commercial Applications," inventors assert that equol may have applications in "... (B) prostate health- benign prostatic hyperplasia (BPH) and prostate cancer... ."
12. It is my usual and ordinary practice to contemporaneously make notes during all my conference calls with other researchers and, more particularly, my collaborators. It is also my usual and ordinary practice to save any other records, such as phone bills and record my daily appointments in a personal diary. Using my personal notes and phone bills, I have refreshed my recollection concerning when and where I discussed information about R- and S-equol enantiomers and their potential application for conditions of the prostate.
13. Exhibit C is a copy of an e-mail communication that I sent to Trent Lund on June 12th, 2002. In this e-mail communication I discussed our collaborative data regarding how equol acts as an anti-androgen and, specifically, 5 α -DHT-equol binding data, as well as, the data on equol's effect on body weight, metabolic and cardiovascular parameters and importance of the properties of

R- and S-enantiomers of equol. Also, in this e-mail, I mentioned that I will be sending Trent a draft of a provisional application relating to these findings.

14. Later on June 12th, 2002, I telephoned Trent Lund to discuss my e-mail communication of June 12th and related matters. Exhibit D is a copy of a telephone bill displaying the record of my telephone call to Trent Lund at the Colorado State University phone number, (970) 491-5638, on June 12th, 2002.
15. Exhibit E is a copy of my personal notes taken during three separate telephone conversations with Trent Lund on July 10th, 11th and 15th, 2002. On July 10th, 2002 I discussed equol-DHT binding and racemic equol vs. R- and S- enantiomers of equol. On July 11th, 2002 Trent and I discussed moving forward with R- and S-equol binding studies. Once more, on July 15th, 2002, Trent and I discussed whether the Colorado State University inventors had the capability of isolating R- and S-equol.
16. Exhibit F is a copy of a telephone bill showing that I called Trend Lund at the Colorado State University phone number, (970) 491-5638, on July 10th, 11th, and 15th, 2002.
17. Exhibit G is a copy of my personal notes taken during a telephone conversation with Kenneth Setchell on July 17th, 2002. This telephone call lasted for over 2 hours, during which Kenneth and I discussed DHT-equol binding and, specifically, binding of racemic equol to DHT. We also

discussed the R- and S-equol enantiomers and their characteristics, such as activity, estrogenic properties and binding to DHT. Furthermore, Kenneth and I discussed synthesis and isolation of R- and S-equol.

18. Exhibit H is a copy of a telephone bill showing that I called Kenneth Setchell at Cincinnati Children's Medical Center phone number, (513) 636-4548, on July 17th, 2002.

19. Exhibit I is a copy of an e-mail communication between Kenneth Setchell and I dated June 07, 2002. In this communication I informed Kenneth Setchell of the finding that equol specifically binds to the DHT-androgen receptor *in vivo* without displacing DHT from the androgen receptor.

20. The above-mentioned Exhibits B-H are evidence that teachings of Setchell and Cole that compositions of equol may include racemic and non-racemic ratios of S-equol to R-equol, and that such compositions may be used for treating and/or ameliorating conditions of the prostate were known and invented by the inventors of the '045 application prior to filing date of the Setchell and Cole reference and prior to the filing date of the '270 priority application. Furthermore, the above-mentioned Exhibits B-H are evidence that both, R- and S-equol possess the unique anti-androgenic ability to antagonize DHT *in vitro* and *in vivo*, making these compounds promising for treating androgen related diseases were also known and invented by the inventors of the '045 application prior to filing date of the Setchell and Cole reference and prior to the filing date of the '270 priority application.

21. The above-mentioned Exhibit I provides further evidence that the mechanism of action of equol, and specifically that equol antagonizes DHT *in vitro* and *in vivo* was disclosed and known by the inventors named on the '045 application prior to the filing date of Setchell and Cole.

22. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on knowledge and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements, and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the U.S. Code and that such willful false statements may jeopardize the validity of the patent application or any patent issuing thereon.

9th February 2009
Date

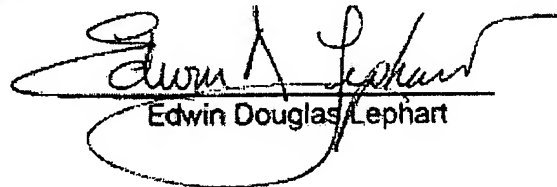

Edwin Douglas Lephart

EXHIBIT A

COMPREHENSIVE - CURRICULUM VITAE

EDWIN DOUGLAS LEPHART

EDUCATION

Ph.D in Physiology (Molecular Biology), The University of Texas Southwestern Medical Center, Dallas, Texas, 1989

M.S. in Experimental Psychology, Brigham Young University, Provo, Utah, 1982

B.S. in Psychology, Brigham Young University, Provo, Utah, 1979

EXPERIENCE

- | | |
|--------------|---|
| 2003-Present | Professor, Department of Physiology and Developmental Biology & The Neuroscience Center |
| 2001-2002 | President, Intermountain Chapter-Society for Neuroscience |
| 1998-2005 | Director- Neuroscience Center at BYU- undergraduate, graduate & research programs |
| 1998-2002 | Associate Professor, Department of Zoology, Neuroscience Center, Brigham Young University, Provo, Utah |
| 1994-1997 | Assistant Professor, Department of Zoology, Cellular Biology Division, Brigham Young University, Provo, Utah |
| 1994 | Assistant Professor, Department of Psychiatry, The University of Texas Southwestern Medical Center at Dallas, Dallas, Texas |
| 1993 | Research Fellow, Department of Internal Medicine, Division of Endocrinology and Metabolism, The University of Texas Southwestern Medical Center at Dallas, Dallas, Texas (Supervisor: Michael J. McPhaul, M.D.) |
| 1992-1994 | Instructor, Department of Molecular Biology, The University of Texas at Dallas, Richardson, Texas |
| 1989-1993 | Research Fellow in Reproductive Endocrinology (NCI & NIH), The Green Center for Reproductive Biology Sciences, The University of Texas Southwestern Medical Center at Dallas, Dallas, Texas (Supervisor: Evan R. Simpson, Ph.D.) |
| 1989-1990 | Lecturer, Human Physiology, The University of Texas Southwestern Medical Center at Dallas, Dallas, Texas |
| 1985-1989 | Medical Technologist, Clinical Chemistry, Parkland and Children's Hospital, Dallas, Texas |
| 1985 | Lecturer, Applied Physiology, The University of Texas Southwestern Medical Center at Dallas, Dallas, Texas |
| 1984-1989 | Predoctoral Fellow (NIH), Department of Physiology, The University of Texas Southwestern Medical Center at Dallas, Dallas, Texas (Supervisors: Sergio R. Ojeda, D.V.M., Jean D. Wilson, M.D., Evan R. Simpson, Ph.D. & Samuel McCann, M.D.) |

- 1984-1985 Instructor, Medical Physiology Student Laboratory, The University of Texas Southwestern Medical Center at Dallas, Dallas, Texas (Supervisor: George Ordway, Ph.D.)
- 1983 Lecturer, Applied Physiology, The University of Oklahoma Health Science Center, Oklahoma City, Oklahoma

INSTRUCTION-

Courses: (Undergraduate) Human⇒ Biology, Neurobiology, Behavioral Neuroscience, Advance Neuroscience, Anatomy & Neuroanatomy, Physiology; (Nursing School) Human⇒ Pathophysiology, (Graduate) Advance Topics of Neuroscience, Physiology; Neuroendocrinology & Reproductive Endocrinology

PROFESSIONAL ORGANIZATIONS

The Society for Neuroscience-member
Society of Cosmetic Chemists-member
American Association of Pharmaceutical Scientists-member

AWARDS

Sigma Xi - The Scientific Research Society

Outstanding Thesis In The College of Social Sciences:

The Effects of Prenatal Stress on Fetal Growth, Development and Placental Transport of 2-Deoxy-D-[³H]-Glucose in the Rat. Brigham Young University, December 1982

National Science Foundation- Early Career Award, 1995-2000

Department of Zoology – Faculty: Outstanding Service and Achievement Award, 1996-97, Brigham Young University, December 1997

College of Biology and Agriculture- Professorship, 2000, Brigham Young University (one year professorship; salary and research stipend)

College of Biology and Agriculture-Thomas Martin Professorship, 2002-2005, Brigham Young University (three-year professorship; salary and research stipend)

BYU University Fellowship- John A. Widtsoe Fellowship, 2004-2005, Brigham Young University (two-year professorship, salary and research stipend)

BYU University Research Award-Karl G. Maeser, 2007, Brigham Young University, stipend

College of Life Science Research Achievement Award, 2007, Brigham Young University, stipend

PROFESSIONAL RESEARCH INTERESTS

Regulation of Estrogen Production Aromatase Cytochrome P450

Biochemistry, Molecular Biology and Endocrinology of 5 α -Reductase

Main Research Interest:

Endocrine Disrupters- Phytoestrogens: Biochemistry, Neural Plasticity, and Aging, Neuro-Endocrine and Behavioral Influences (reproductive endocrine, learning, metabolism, memory and cognition)

REFERENCES

1. Daniel L. Simmons, PhD, Professor, Chemistry/Biochemistry, Brigham Young University, E-280 BNSN, Provo, Utah 84602, (801) 422-4441, email: Dan_Simmons@byu.edu
2. Kenneth D.R. Setchell, PhD., Professor, Pediatrics, Director- Clinical Mass Spectrometry, Children's Hospital Medical Center, Rm 028, 3333 Burnet Avenue, Cincinnati, Ohio 45229, (513) 636-4548, email: KSetchell@aol.com
3. Tamas Horvath, PhD., DVM, Professor, Department of Ob/Gyn, Head - Reproductive Neuroscience Unit, Yale Medical School, 333 Cedar Street, New Haven, CT 06510. (203) 785-4597, email: tamas.horvath@yale.edu
4. Greg F. Burton, PhD., Professor, Chemistry/Biochemistry, Brigham Young University, C-206 BNSN, Provo, Utah 84602, (801) 422-4917, email: gfb2@email.byu.edu

JOURNAL - EDITORIAL BOARD-Advisor

Reproductive Biology and Endocrinology 2002-present

JOURNAL- EDITORIAL REVIEW

American Journal of Clinical Nutrition
Applied Journal of Physiology
Biochemical Pharmacology
Biological Psychiatry
Biology of Reproduction
Brain Research- (Developmental Brain Research, Molecular Brain Research, Brain Research and Brain Research Reviews)
Brain Research Bulletin
Cell and Molecular Endocrinology
Chemico-Biological Interactions
Comparative Biochemistry and Physiology
Endocrine
Endocrinology
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European Journal of Clinical Nutrition
Hormones & Behavior
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Journal of Chemical Neuroanatomy
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Journal of Neurochemistry
Journal of Neuroendocrinology
Journal of Neuroscience

Journal of Experimental Zoology
Journal of Society for Gynecologic Investigation
Neuroendocrinology
Neuropharmacology
Neuroscience Letters
Neurotoxicology and Teratology
Pharmacology, Biochemistry and Behavior
Physiology and Behavior
Royal Society (London) Science
Trends in Neuroscience

NATIONAL AND INTERNATIONAL GRANT REVIEW/EVALUATION:

**NATIONAL SCIENCE FOUNDATION (WASHINGTON, D.C., USA)-
1995-1999**

**MEDICAL RESEARCH COUNCIL (LONDON, ENGLAND)-
1997-1999, 2001**

**NATIONAL INSTITUTES OF ENVIRONMENTAL HEALTH SCIENCES –
1999**

THE ISRAEL SCIENCE FOUNDATION (JERUSALEM, ISRAEL) – 2000

USDA- external review – 2001 - 2005

RESEARCH GRANTS

1994-2001

BYU COLLEGE OF BIOLOGY (PDC) PROFESSIONAL DEVELOPMENT

PI: Edwin D. Lephart Brain Aromatase and 5 α -Reductase During
Prenatal and Postnatal Development, Sept. 1994 \Rightarrow Aug. 2001:
Grant # 2-62851 Total Direct Costs: \$ 19,600.00

1995-2001

NATIONAL SCIENCE FOUNDATION

PI: Edwin D. Lephart Brain Aromatase Cytochrome P-450 and CNS
Development, Jul. 1995 \Rightarrow Jun. 2001: Grant # IBN-9507972
Total Direct Costs: \$ 458,000.00

1996-97

NATIONAL SCIENCE FOUNDATION

PI: Edwin D. Lephart Brain Aromatase Cytochrome P-450 and CNS Development (REU-SUPPLEMENT) Jul. 1995 ⇒ Jun. 1996: Grant # IBN-9507972

Total Direct Costs: \$ 13,300.00

1998

BYU Research Office/Bio-Aq and Social Sci College Support

PI: Edwin D. Lephart Establishment of a Neuroscience Center at BYU
March 1998 ⇒ March 1999:

Total Direct Costs: \$ 80,000.00

1999

BYU Research Office/Bio-Aq and Social Sci College Support

PI: Edwin D. Lephart Neuroscience Center at BYU

February 1999 ⇒ December 1999:

Total Direct Costs: \$ 31,000.00

NATIONAL SCIENCE FOUNDATION

PI: Edwin D. Lephart REU Site for Undergraduates in Neuroscience
May 2000 ⇒ August 2003: Grant # DBI – 9912126

Total Direct Costs: \$ 174,000.00

BYU Research Office

PI: Edwin D. Lephart Neuroscience Center at BYU-undergraduate research
January 2001 ⇒ December 2001:

Total Direct Costs: \$ 34,650.00

2001

BYU Research Office

PI: Edwin D. Lephart Neuroscience Center at BYU-undergraduate research
January 2002 ⇒ December 2002:

Total Direct Costs: \$ 31,500.00

2002

UNITED STATES DEPARTMENT OF AGRICULTURE (USDA)

PI: Edwin D. Lephart Neuroendocrine and Metabolic Disruption by Dietary Soy-Derived Phytoestrogens

Sept 2002 ⇒ August 2005: Grant # 2002-00798

Total Direct Costs: \$ 168,000.00

2004

BYU TECHNOLOGY TRANSFER OFFICE

PI: Edwin D. Lephart Equol Technology

Jan 2004 ⇒ Dec 2004: Grant # 19-223566

Total Direct Costs: \$ 24,000.00

UNITED STATES DEPARTMENT OF AGRICULTURE (USDA)

PI: Edwin D. Lephart The Central Nervous System, Aging & Behavior: Influence of Dietary Soy Phytoestrogens

Dec 2004 ⇒ November 2008: Grant # 2004-01811

Total Direct Costs: \$ 400,000.00

BYU RESEARCH OFFICE

PI: Edwin D. Lephart John A. Widtsoe Fellowship

Sept 2004 ⇒ August 2006: Grant # 19-224568

Total Direct Costs: \$ 20,000.00

NATIONAL INSTITUTES OF HEALTH (NIH)

PI: Merrill Christensen Selenium, Isoflavones and Prostate Cancer Risk

Apr 2004 ⇒ Mar 2006: Grant # NIH 1 R15 CA 106374-01

Total Direct Costs: \$ 150,000.00

Co-PI: *Edwin D. Lephart* percent effort 10 %

2006

NATIONAL INSTITUTES OF HEALTH (NIH)

PI: Merrill Christensen Selenium, Isoflavones and Prostate Cancer Risk
Renewal

Apr 2006 ⇒ Mar 2008: Grant # 1R15CA122235-01A1

Total Direct Costs: \$ 150,000.00

Co-PI: *Edwin D. Lephart* percent effort 15 %

2008

NATIONAL INSTITUTES OF HEALTH (NIH) (NCCAM)

PD/PI: *Merritt Andrus and Edwin Lephart*

Polyphenolic Analogs for Disease Prevention

Sept 2008 ⇒ Aug 2013: Grant # TBA-Pending review

Total Direct Costs: \$ 1,600,000.00

PD/PI: Edwin D. Lephart percent effort 25 %

Multiple PD/PIs per NIH guidelines

BYU RESEARCH OFFICE

PI: *Edwin D. Lephart* Mentoring (Phytoestrogen) Research

March 2008 ⇒ December 2008: Grant # 20-223610-137

Total Direct Costs: \$ 20,000.00

BYU TECHNOLOGY/ LSCOLLEGE OFFICE

PI: *Edwin D. Lephart* Phytoestrogen Technology/Research

April 2008 ⇒ unrestricted funds: Grant # 20-223610-307

Total Direct Costs: \$ 18,850.00

Graduate Committees

	Name	Chair or Member	M.S. or Ph.D.	Date-Completion
1.	Adrian Hutbert	Member	Ph.D.	August 1996
2.	David Ladle	Chair	M.S.	June 1997
3.	Nathan Jacobson	Chair	M.S.	June 1997
4.	Aaron Starbuck	Chair	Honors	August 1999
5.	Emily Brinton	Chair	Honors	August 1999
6.	Jianfeng Zhu	Member	Ph.D.	August 2001
7.	Trent Lund	Member	M.S.	December 1999
8.	Scott Weber	Chair	M.S.	August 2000
9.	David Salyer	Member	M.S.	December 1999
10.	Emily Stuart	Chair	M.S.	December 2000
11.	Trent Lund	Member	Ph.D.	August 2000
12.	Jacob Ong	Chair	Honors	August 2001
13.	Christy W. Spackman	Chair	Honors	August 2001
14.	Amy Curtis	Chair	Honors	August 2001
15.	Shawn Crook	Member	M.S.	August 2001
16.	Li Hong Bu	Chair	Ph.D.	August 2005
17.	Vivek Ramakrishnan	Member	Ph.D.	December 2002
18.	Naomi Hunshaker	Member	Ph.D.	August 2009
19.	Russell Legg	Member	M.S.	August 2007
20.	Kimberly Fabick	Chair	M.S.	August 2008
21.	Crystal Blake	Chair	M.S.	August 2008
22.	Crystal Blake	Chair	Ph.D.	August 2011

Department (D) , College (C) and University (U) Committees

Undergraduate Research Trainee- Supervisor- College of Education, 1994-2001 (D, C)
 Self-Study Evaluation, Department of Zoology - Member, co-author- Data Analysis/Statistical Profile Section, 28-1 through 28-16, 1994-95 (D,U)
 Adam Computer Program evaluation -Member, for Human Anatomy, Zool 260- 1994-95 (D); Chaired by Dr. Mark Nielson, Department of Biology, University of Utah, SLC, UT (U)
 Coordinator- Zoology/Cellular Biology Division Seminars, 1995 (D)
 Zoology Department Seminar Coordinator-1995-1997 (D)
 Reviewer for the Zoology Graduate Research Fellowship Awards- 1995-96 (D)
 Bio-Ag College Symposium Committee Member-1995-1997 (C)
 Strengthening the Students Committee-Member-1996-1997 (D)
 Chairman- Curriculum and Catalog Committee-1997-1998 (D)
 Endowment Chairman-1999-2001 (D)
 Department Physiology/Developmental Biology, Seminar Coordinator-2001-2003 (D)
 Department Physiology/Developmental Biology, Funding Comm. Member-2005- (D)
 Department Physiology/Developmental Biology, Research Comm. Chair-2006- (D)

ABSTRACTS PRESENTED AT INTERNATIONAL MEETINGS

1. **Lephart, E.D.** and S.R. Ojeda. Developmental Regulation of Hypothalamic and Pituitary Aromatase Activity in the Male Rat. Ann. Mtg. Neuroscience, Toronto, Canada, 1988.
2. **Lephart, E.D.**, R.W. Rhees and D.E. Fleming. Alterations in Maternal Regulatory Behaviors and Placental Transport in Environmental Stressed Rats. Ann. Mtg. Am. Soc. Zoologists, San Francisco, CA, 1988.
3. **Lephart, E.D.** Prenatal Hypothalamic Aromatase Activity in Organotypic Cultures. Ann. Mtg. Endocrine Soc., Seattle, WA, 1989.
4. **Lephart, E.D.**, S.R. Ojeda, E.R. Simpson, J.D. Wilson and M.J. McPhaul. Detection of Brain Aromatase P-450 Messenger Ribonucleic Acid: Comparison to Aromatase Activity During Prenatal Development in the Rat. Sero Symposium, USA, Neuroendocrine Regulation of Reproduction, Napa, CA, 1989.
5. Doody, K.J., **E.D. Lephart**, D. Stirling, M.C. Lorence, J.I. Mason, R.R. Magness and E.R. Simpson. Expression of mRNA Species Encoding Steroidogenic Enzymes in Rat Ovaries. Ann. Prog. Soc. Gynecologic Investigation, San Antonio, TX, 1990.
6. Trzeciak, W.H., **E.D. Lephart**, S.Andersson and E.R. Simpson. 5 α -Reductase mRNA and Content and Enzyme Activity in Rat Adrenal are Sex Hormone Dependent. Ann. Mtg. Adrenal Cortex, Atlanta, GA, 1990.
7. **Lephart, E.D.** and E.R. Simpson. Detection of Brain Messenger Ribonucleic Acid Encoding Aromatase Cytochrome P-450 and 5 α -Reductase: Comparison to Aromatase and 5 α -Reductase Activities During Prenatal Development in the Rat. Ann. Mtg. Endocrine Soc., Atlanta, GA, 1990.
8. Corbin, C.J., **E.D. Lephart**, M.J. McPhaul, K.J. Doody and E.R. Simpson. Isolation of a Full-Length cDNA Insert and Genomic DNA Encoding Rat Aromatase Cytochrome P-450. International Symposium on Microsomes and Drug Oxidations, Stockholm, Sweden, 1990.
9. **Lephart, E.D.** and K.J. Doody. Inverse Relationship Between Ovarian Aromatase Cytochrome P-450 and 5 α -Reductase Enzyme Activities and mRNA Levels During the Estrous Cycle in the Rat. Ann. Mtg. Endocrine Soc., Washington, D.C., 1991.

ABSTRACTS PRESENTED AT INTERNATIONAL MEETINGS

10. Sanghera, M., E.R. Simpson and **E.D. Lephart**. Immunocytochemical Distribution of Aromatase in the Rat Brain using Synthetic Peptide-Generated Polyclonal Antibodies. Ann. Mtg. Endocrine Soc., Washington, D.C., 1991.
11. **Lephart, E.D.**, D. Husmann and E.R. Simpson. Inhibition of Brain, but not Pituitary, 5 α -Reductase Activity by MK-906 in Male Rats - Comparison with the Anti-androgen Flutamide and Exogenous Dihydrotestosterone Treatment. Soc. For The Study of Reproduction, Vancouver, British Columbia, 1991.
12. **Lephart, E.D.**, M.J. McPhaul and E.R. Simpson. Ovarian Aromatase Cytochrome P-450 mRNA Correlates with Enzyme Activity and Serum Estradiol Levels in Anestrous, Pregnant and Lactating Rats. Serono Symposia, USA, Molecular Basis of Reproductive Endocrinology, Vancouver, British Columbia, 1991.
13. Husmann, D. and **E.D. Lephart**. Establishment of an Animal Model to Investigate the effect of Brain and Pituitary 5 α -Reductase Activity on Neural Development and Sexual Behavior. Ann. Mtg. American Academy of Pediatrics, Toronto, Canada, 1991.
14. Herbst, M.A. and **E.D. Lephart**. Promoter Characterization of Aromatase Cytochrome P-450 Gene expression in Rat Ovary, a Rat Leydig Tumor Cell Line and Fetal Rat Brain Tissue. Ann. Mtg. Endocrine Soc., San Antonio, TX, 1992.
15. **Lephart, E.D.**, M.J. McPhaul, J.D., Wilson, M.W. Kilgore, S.R. Ojeda and E.R. Simpson. Divergence Between Cytochrome P450 Brain Aromatase mRNA Levels and Enzymatic Activity During Perinatal Development. The Third International Conference on Aromatase, Bologna, Italy, 1992.
16. M.J. McPhaul, M.A. Herbst, M. Young and **E.D. Lephart** and J.D. Wilson. Diverse Mechanisms of Control of Aromatase Gene Expression. The Third International Conference on Aromatase, Bologna, Italy, 1992.
17. **Lephart, E.D.**, M.A. Herbst, E.R. Simpson and M.J. McPhaul. Promoter Characterization of Aromatase Cytochrome P-450 Gene Expression in Rat Ovary, Fetal Brain, and a Leydig Tumor Cell Line: Evidence for the Existence of Brain Specific Aromatase Transcripts. Ann. Mtg. Experimental Biology, FASEB, New Orleans, Louisiana, 1993.
18. Roselli, C.E., S.E. Abelgadir, **E.D. Lephart**, M.J. McPhaul and J.A. Resko. Androgens Regulate Aromatase Cytochrome P450 mRNA in Rat Brain. Ann. Mtg. Soc. Neuroscience, Washington, D.C., 1993.

ABSTRACTS PRESENTED AT INTERNATIONAL MEETINGS

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1. L.J. Lu, J.A. Tice, F.L. Bellino (**E.D. Lephart** - effects on cancers - section presentation/discussion leader). 2001 Phytoestrogens and healthy aging: gaps in knowledge-An NIH workshop report. *Menopause* 8:157-170.

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9. Lund, T.D., K.D.R. Setchell, **E.D. Lephart**, R.J. Handa. 2004. Unique Endocrine Properties of the Phytoestrogen Metabolite Equol. *Recent Research Developments in Endocrinology* 4: 181-208.

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1. Current Studies on 5 α -Reductase in Neural and Adrenal Tissue. Merck Sharp & Dohme Research Laboratories. Rahway, NJ., January 11, 1991.
2. 5 α -Reductase Enzyme Activity and mRNA Content in Adrenal, Ovary and Brain. Department of Zoology, Brigham Young University. Provo, UT., November 7, 1991.
3. Neural Cytochrome P-450 Aromatase and Sexual Differentiation of the Brain. Psychology Forum, Brigham Young University. Provo, UT., November 7, 1991.
4. Aromatase and 5 α -Reductase Studies in the Rat. Proctor and Gamble Research Laboratories. Cincinnati, OH., April 6, 1992.
5. Brain Aromatase: Location and Molecular Biology Studies. Department of Obstetrics and Gynecology, Yale Medical School. New Haven, CT., September 4, 1992.
6. Aromatase Cytochrome P-450 and the Sexual Differentiation of the Brain: Localization, Regulation and Molecular Biology Studies. Department of Cell Biology and Anatomy, Texas Tech Medical School. Lubbock, TX., October 19, 1992.
7. Molecular Biology Studies on Brain 5 α -Reductase and Cytochrome P-450 Aromatase. Department of Pharmacology, The University of Pittsburgh School of Medicine. Pittsburgh, PA., March 19, 1993.
8. Sexual Differentiation of the Brain: Current Studies on 5 α -Reductase and Aromatase. Department of Zoology, The University of Texas at Austin. Austin, TX., March 26, 1993.
9. Molecular Biology Studies on Androgen Metabolism by Cytochrome P-450 and 5 α -Reductase. Comprehensive Cancer Center, Arthur G. James Cancer Hospital and Research Institute, The Ohio State University School of Medicine. Columbus, OH., August 5, 1993.
10. Psychotropic Sex Steroids and CNS Differentiation. Department of Psychology, Michigan State University. East Lansing, MI., January 24, 1994.
11. The Biological Significance of 5 α -Reductase and Aromatase in Brain Development and Function. Department of Zoology, Brigham Young University. Provo, UT., February 8, 1994.

INVITED CONFERENCES AND SEMINARS

12. Neurobiology of 5 α -Reductase and Aromatase in CNS Differentiation. Department of Biology, Texas Women's University, Denton, TX., February 15, 1994.
13. National Institutes of Health (NIH), Conference. Department of Health and Human Services, National Institute of Neurological Disorders and Stroke (NINDS), Bethesda, MD., October 24-25, 1994.
14. Perinatal Brain Aromatase: Enzymatic and Molecular Implications. Workshop on Steroid Hormones and Brain Function. Breckenridge, CO., April 1-5, 1995.
15. Molecular Biology Studies on Brain Aromatase Cytochrome P450. Department of Neurobiology, UCLA Medical School, Los Angeles, CA., November 10, 1995.
16. Symposium Speaker, Molecular Aspects of Brain Aromatase Cytochrome P450, IV International Aromatase Conference, Tahoe City, CA, June 8-11, 1996.
17. Biological Sciences Conference, Molecular and Enzymatic Characteristics of Brain Aromatase Cytochrome P450, National Science Foundation, Arlington, VA., June 24-25, 1996.
18. Sigma Xi Lecture of the Month, Conversion of Testosterone to Estrogens in the Brain. Enzymatic and Molecular Biology Studies. Brigham Young University, Provo, UT., October 17, 1996.
19. Neural Development and Function: Influence of Brain Aromatase, 5 α -Reductase and Calcium-Binding Proteins. The University of Texas at Dallas, Richardson, TX., March 20-21, 1997.
20. CNS Development and Function: Influence of Aromatase, 5 α -Reductase, Calcium-Binding Proteins and Phytoestrogens. Department of Cell Biology and Biochemistry, Texas Tech Medical School. Lubbock, TX., March 25-27, 1998.
21. NSF Career Program P.I. Meeting. Neuroscience: Steroid Hormones, Calcium-Binding Proteins and Undergraduate Research, National Science Foundation, Arlington, VA., January 10-12, 1999.
22. National Institutes of Health (NIH) Workshop on Phytoestrogens and Healthy Aging: A Research Agenda. Workshop speaker-National Institute on Aging (NIA), Phoenix, AZ, June 2-4, 1999. Published in Menopause 8:157-170, 2001.

INVITED CONFERENCES AND SEMINARS

23. The Neuroscience Major at BYU. Forum speaker-Ricks College, Departments of Psychology and Biology, Rexberg, ID, October 14-15, 1999.
24. Environmental Signaling and the CNS. Symposium Speaker. Satellite Meeting to The Annual Meeting For The Society For Neuroscience, Tulane Environmental Research Center, New Orleans, LA, November 4, 2000.
25. Brain Aromatase and Memory Effects of Dietary Soy Phytoestrogens. Grand Rounds, The Barrow Neurological Institute, St. Joseph's Hospital, Phoenix, AZ. 12th January, 2001.
26. Brain Androgen and Progesterone Metabolizing Enzymes: Synthesis, Distribution and Function. Steroids and Nervous System. Invited Speaker-International Neuroscience Scientific Meeting, Villa Gualino, Torino, Italy, February 11-14, 2001.
27. Dietary Soy Phytoestrogens Alter Sexually Dimorphic Hypothalamic Nuclei in Adult Rats. Experimental Biology 2001, Symposium speaker on Brain Aging and Nutrition, Orlando, FL. March 31- April 4, 2001.
28. Quantitative and Qualitative Methodologies for Brain Aromatase Enzymatic Activity and mRNA Levels, Invited Speaker, Environmental Protection Agency (EPA), Reproductive Endocrinology Division, Research Triangle Park, NC, May 8, 2001.
29. Dietary Soy Phytoestrogens Produce Anxiolytic Effects in the Elevated Plus Maze. Exposure to Estrogenic Disrupters During Development: Effects of Brain and Behavior. Invited Symposium Speaker - International Neurotoxicology Meeting, Annual Neurobehavioral Teratology Mtg., Montreal, Canada, June 24-27, 2001.
30. Brain Function and the Impact of Phytoestrogens Diets in Rat Models. Invited Symposium Speaker on The Effects of Dietary Phytoestrogens on Reproductive, Toxicity and Carcinogenicity Studies- American Association for Laboratory Animal Science, 52nd National Meeting, Baltimore, MD, October 21-25, 2001.
31. Phytoestrogens- Generating Artificial Data in Animal Research? President's Address, Fall Intermountain Society for Neuroscience Meeting, Thanksgiving Point, Utah, October 25, 2001.
32. Herbs, Phytoestrogens, and Current Fads. Invited Conference Speaker, A Woman's Journey-Leading Your Patients to Health and Wellness, St. Joseph Hospital, Denver, CO, October 26, 2001.

INVITED CONFERENCES AND SEMINARS

33. Effects of Dietary Soy Phytoestrogens on Brain Aromatase, Anxiety Behavior, Neural Structure and Memory. Invited Symposium Speaker, 4th International Symposium on the Role of Soy in Preventing and Treating Chronic Disease, San Diego, CA, Nov. 4-7, 2001
34. Neurobehavioral Effects of Dietary Soy Phytoestrogens. Invited seminar speaker, Department of Biology, Texas Woman's University, Denton, TX, Feb 14, 15, 2002.
35. Dietary Phytoestrogens Effects on Brain and Behavior. Invited seminar speaker, Department of Veterinary Biosciences, University of Illinois, Urbana, IL, Mar 1, 2002.
36. Estrogens and Phytoestrogens Effects on Brain Development and Function. Invited seminar speaker, Department of Anatomy and Cell Biology, Howard University, Washington, D.C., May 3rd, 2002.
37. Hormonal and Metabolic Effects of Dietary Phytoestrogens. Invited seminar speaker, Department of Physiology, The University of Texas Health Center, at San Antonio, San Antonio, TX., May 9-10, 2002.
38. Estrogen and Phytoestrogens: Brain Plasticity and Function. Invited symposium speaker, International Congress on Hormonal Steroids and Hormones and Cancer, Fukuoka, Japan, October 21-25, 2002.
39. A Receipt For Soy-Isoflavones Influencing Brain Structure and Behavior. Symposium Speaker, 2004 Hawaii International Conference on Sciences, Honolulu, HI, Jan. 15-18, 2004.
40. Is There Hope for Baldness? Hormonal Actions of Androgens (and Estrogens) in Skin and Hair. Invited speaker, Intermountain Chapter – Society of Cosmetic Chemists, Salt Lake City, UT, May 19, 2004.
41. Diet, Brain and Behavior: Influence of Isoflavones. Invited workshop speaker, Society for Behavioral Neuroscience, Austin, TX, June 22, 2005.
42. Gender Differences in Neural Structures. Invited Symposium speaker, American Psychology Association, Washington, D.C., August 18-21, 2005.
43. Effects of Dietary Estrogens on Developmental, Endocrine and Toxicity Studies. Invited Conference Speaker, National Institutes of Environmental Health Sciences (NIEHS), Research Triangle Park, NC, Sept. 14-15, 2005.
44. Phytoestrogens: Brain, Hormones & Behavior, Keynote Speaker, Northeastern Society for Neuroscience, New York, New York, April, 8, 2006

45. Project Directors Workshop, NRI Bioactive Food Components for Optimal Health, Invited Speaker at the United States Department of Agriculture (USDA), Washington, D.C., June 25-26, 2007.

CONTINUING PHARMACEUTICAL EDUCATION CREDIT

American Society of Consultant Pharmacists

ACPE. I.D. Univ. Prog. No. 203-000-02-197-C01

Dementia and Alzheimer's Disease: A Multidisciplinary Assessment of Diagnosis and Management in LTC. June 5, 2002. 1.0 hour credit

MEDIA-PRESS CONFERENCES

The Endocrine Society-panel "The Dietary Estrogens." Drs. **E.D. Lephart**, T.D. Lund, A. Kung & L Lu. 83rd Annual Meeting of The Endocrine Society, Denver, CO, Friday, June 22, 2001.

PRESS RELEASE: MARCH 2004 – EQUOL TECHNOLOGY

CONTINUING SOCIETY OF COSMETIC CHEMISTS EDUCATION CREDIT

1. Cosmetic Formulations, Instructors: Ken Klein & Mark Chandler, New York City, New York, December 6 & 7th, 2005.
2. Advanced Skin Care, Instructor: Randy Wickett, PhD, Boston, MA, May 10, 2006
3. How the Cosmetic Ingredient Review (CIR) Program Impacts the Cosmetic Chemist, Alan Anderson, PhD, CTFA, Boston, MA, May 11, 2006

EXHIBIT B

Item B

COLORADO STATE UNIVERSITY
DISCLOSURE OF INVENTION

**PROPRIETARY INFORMATION
 NOT TO BE DISCLOSED**

File #: CSU- 03-006
 Date of Disclosure: 8-6-02

THE INFORMATION CONTAINED IN THIS FORM IS CONFIDENTIAL AND MAY NOT BE DISTRIBUTED
 OR COPIED WITHOUT WRITTEN PERMISSION

Title: Anti-Androgen effects of Equol

Full Name		% Cont.	Department & Address (Room Number)	Dept. Phone	Dept. Fax
First	Last				
Robert	Handa		Biomedical Sciences W215	491-7130	491-7907
Trent	Lund		Biomedical Sciences W214	491-5638	491-7907
Edwin	Lephart		Brigham Young University (Utah)		
Kenneth	Setchell		Cincinnati Children's Hospital (Ohio)		

Main
Contact

Stage of Development	Date	Location	Persons, Records or Supporting Facts
A. First Disclosure to Others	May 2001	CSU	TL, RH, EL - Lab Notes
B. First sketch or drawing	May 2001	CSU	TL, RH, EL - Lab Notes
C. First Written Records	5/30/2001	CSU	TL, Computer File/notes
D. First device or prototype			
E. First successful operational test			

List notebook entries, reports, manuscripts (published, in press, or planned submission date),
 drawings etc that you feel are relevant
 See attached (pages 1-8)

If disclosed outside the University or CSURF, identify individuals and or agencies and date of
 disclosure (In the case of biological materials please provide any dates and accession numbers for
 deposit to GenBank, ATCC etc.

Edwin Lephart (Brigham Young University) May 2001
 Kenneth Setchell (Cincinnati Children's Hospital) December 2001

If known, please list any companies that may be interested in commercializing the invention

Abbott Laboratories, Eli Lilly and Company, GlaxoSmithKline, Merck and Company, Pfizer, Proctor & Gamble, Wyeth, Solvay,
 Wyeth, Johnson & Johnson, Aventis, Unimed, Upjohn, Pharmacia, NuSkin, MaryKay, Nature Sunshine, GNC, Enrich, etc.

Brief Summary of Invention (paper(s), more complete descriptions, etc., should be appended, but please also give a brief summary):

The phytoestrogen Equol acts as an Anti-Androgen. Specifically equol binds directly to the androgen, 5 α -Dihydrotestosterone (5 α -DHT) but does not bind the androgen receptor complex nor does equol bind other androgens (i.e. testosterone, DHEA).

Practical and Commercial Applications: The applications in health, disease, etc., of equol, and related molecules indicate broad and important usage for conditions (that would bind circulating 5 α -DHT, without altering the androgen receptor complex), such as: (A) female- and male-pattern baldness and facial and body hair growth; skin health- acne, anti-aging and anti-photo aging, skin integrity (collagen and elastin robustness), (B) prostate health- benign prostatic hyperplasia (BPH) and prostate cancer, (C) Alzheimer's disease and emotional, mental health issues, such as, mood, depression, anxiety and learning and memory by reducing the 5 α -steroid metabolites (covering androgens and presumably progesterone) that are potent modulators of the GABA_A receptor in the brain that influences all of the brain characteristics above and, (D) general regulatory behaviors and effects, such as, food and water intake, weight gain (and loss), metabolism of lipids, blood pressure changes, thyroid, glucose, leptin, insulin and prostate weight changes and the influence on the immune system.

Advantages over State-of-the-Art: To date there are no known compounds that act to inhibit androgen action by specifically binding ligand such as dihydrotestosterone. The advantage of this approach in terms of anti-androgenic properties is that the androgen receptor -DHT complex can be targeted without altering the androgen receptor - testosterone complex. This has decided advantages over compounds which target the androgen receptor directly (non-discriminatory).

Please list below all sources of funding for materials, equipment and/or salaries of all personnel involved in making the invention (check where appropriate):

1. XX Some / all (circle one) funds from unrestricted University/Departmental budget.

2. XX Some / all (circle one) funds from federal or non-profit granting agencies:

Agency	Grant or Contract #	CSU Acct #
NIH	NS39951	534538 - Salary for TL

3. Some / all (circle one) funds from companies or other organizations

Company/Organization	Grant or Contract #	CSU Acct #

The undersigned hereby declare(s) that they (he/she) are (is) the true and only originator(s) of the invention disclosed herein at Colorado State University, and that the invention arose in the course of work at or on behalf of Colorado State University and will be handled according to University Policy (Section J of the Academic Faculty and Administrative Professional Manual).

The following information regarding home addresses and Social Security Numbers is required if any patent applications are to be filed on the disclosed technology.

The undersigned hereby declare(s) that they (he/she) are (is) the true and only originator(s) of the invention disclosed herein at Colorado State University, and that the invention arose in the course of work at or on behalf of Colorado State University and will be handled according to University Policy (Section J of the Academic Faculty and Administrative Professional Manual).

The following information regarding home addresses and Social Security Numbers is required if any patent applications are to be filed on the disclosed technology.

MAIN CONTACT Inventor 1: Robert J Handa _____ Sign: <u>[Signature]</u> _____ e-mail: <u>Robert.handa@colostate.edu</u> _____ Citizenship: <u>USA</u> _____ Home Add: <u>1132 Crestway Court</u> _____ <u>Fort Collins, CO 80526</u> _____ Soc.Sec.#: _____		Inventor 2: <u>Trent D Lund</u> _____ Sign: <u>[Signature]</u> _____ e-mail: <u>tlund@colostate.edu</u> _____ Citizenship: <u>USA</u> _____ Home Add: <u>304 Butch Cassidy Dr</u> _____ <u>Fort Collins, Colorado 80524</u> _____ Soc.Sec.#: _____	
Inventor 3: <u>Edwin D Lephart</u> _____ Sign: <u>[Signature]</u> _____ e-mail: <u>edwin.lephart@colostate.edu</u> _____ Citizenship: <u>USA</u> _____ Home Add: <u>1702N Meadowlark Rd</u> _____ <u>Orem, UT 84087</u> _____ Soc.Sec.#: _____		Inventor 4: <u>Kenneth D R Setchell</u> _____ Sign: _____ e-mail: _____ Citizenship: _____ Home Add: _____ Soc.Sec.#: _____	
Inventor 5: _____ Sign: _____ e-mail: _____ Citizenship: _____ Home Add: _____ Soc.Sec.#: _____		Inventor 6: _____ Sign: _____ e-mail: _____ Citizenship: _____ Home Add: _____ Soc.Sec.#: _____	

You may choose to perform your own patent searches in addition to those that may be performed by CSURF. You can access patent databases at the following web sites:

IBM Intellectual Property Network: <http://www.patents.ibm.com/>
 U.S. Patent & Trademark Office: <http://www.uspto.gov/>

EXHIBIT C

Subject: Equol Review Provisional Patent

Date: Wed, 12 Jun 2002 15:10:09 -0600

From: Edwin Lephart <Edwin_Lephart@byu.edu>

To: TLund@Colostate.edu

Trent,

I know that you are very busy, so I took the liberty of generating a brief review/draft document for our upcoming equol provisional patent (I will fax this to you since my email has been up and down). Please have Bob Handa take a look at this if you feel it appropriate. It contains a short background section (mostly from my USDA grant application on phytoestrogens), a concise summary of how equol acts as an anti-androgen, specifically binding 5alpha-DHT, plus recent data on body weight, metabolic and cardiovascular parameters and finally a succinct statement of the important and novel properties of the R and S isomers of equol as an anti-androgen. This data along with the estrogen receptor binding data will make a novel story and provide for a good marketing tool for both scientific mtgs outlets and future human health applications. I will contact Ken Setchell in the near future to discuss this review/draft and obtain his ideas and suggestions, etc... I know that you will be cutting out for your vacation soon so please get back to me ASAP. If I can be of any assistance please do not hesitate to contact me. Let me know what your thoughts are on this.

Finally, I will be sending you the Endo poster abstract draft soon.

I will call you later to see if you received this in good order.

Best Wishes

Eddie

EXHIBIT D

June 2002

Billing Detail for Billable Calls

Date	Type	Proj	From Number	From Location	To Number	To Location	Time	Duration	Amount
Account: 11223500-6140-00000 (Cont.)									
Calls for: EVANS, R. PAUL (Cont.)									
Total for EVANS, R. PAUL								87.7	7.02
Calls for: JOHNSON, BRIAN									
06/19	DA		801 555-1212	Dir Assistanc	3:07 p.m.			1.1	0.50
Total for JOHNSON, BRIAN								1.1	0.50
Calls for: LEPHART, EDWIN D.									
05/23	USA		IP PHONE	435 940-2122	Park City	1:02 p.m.		1.0	-0.09
05/23	USA		IP PHONE	435 940-2122	Park City	1:02 p.m.		1.0	-0.09
05/23	USA		IP PHONE	303 419-1299	Colorado	1:23 p.m.		2.6	-0.23
05/23	USA		IP PHONE	303 419-1299	Colorado	1:23 p.m.		2.6	-0.23
05/24	USA		IP PHONE	765 966-1885	Indiana	10:05 a.m.		1.7	-0.15
05/24	USA		IP PHONE	765 966-1885	Indiana	10:05 a.m.		1.7	-0.15
05/24	USA		IP PHONE	970 491-5638	Colorado	5:03 p.m.		1.2	-0.11
05/24	USA		IP PHONE	970 491-5638	Colorado	5:03 p.m.		1.2	-0.11
06/03	USA		IP PHONE	970 491-7130	Colorado	1:29 p.m.		32.8	2.95
06/04	USA		IP PHONE	505 471-3232	New Mexico	11:26 a.m.		7.3	0.66
06/05	USA		IP PHONE	505 471-3232	New Mexico	1:41 p.m.		5.3	0.48
06/05	USA		IP PHONE	513 636-4548	Ohio	2:32 p.m.		0.9	0.08
06/06	USA		IP PHONE	314 982-2646	Missouri	1:56 p.m.		1.4	0.13
06/06	USA		IP PHONE	608 277-2016	Wisconsin	2:46 p.m.		48.0	4.32
06/10	USA			970 491-5638	Colorado	3:56 p.m.		0.4	0.04
06/12	USA			808 831-3500	Hawaii	3:45 p.m.		5.8	0.52
06/12	USA			970 491-5638	Colorado	4:13 p.m.		48.9	4.40
06/13	USA		IP PHONE	970 491-7130	Colorado	1:11 p.m.		20.4	1.84
06/13	USA	2-0700	WIDB 574B	970 491-7907	Colorado	2:24 p.m.		5.8	0.52
06/24	USA		IP PHONE	608 277-2016	Wisconsin	2:19 p.m.		1.1	0.10
06/26	UT		IP PHONE	801 581-3404	Salt Lake Cit	10:15 a.m.		6.5	0.46
Total for LEPHART, EDWIN D.								171.6	15.34
Calls for: PORTER, JAMES									
06/05	UT		IP PHONE	801 587-7706	Salt Lake Cit	4:34 p.m.		4.5	0.32
06/12	USA			650 292-2080	California	3:05 p.m.		7.0	0.63
06/13	USA	2-0700	WIDB 574B	650 259-6891	California	12:59 p.m.		0.8	0.07
06/26	USA		IP PHONE	612 624-2652	Minnesota	8:20 a.m.		5.5	0.50
Total for PORTER, JAMES								17.8	1.52
Calls for: RHEES, R. WARD									
05/23	UT		IP PHONE	801 255-8899	Midvale	8:53 a.m.		2.0	-0.14
05/23	UT		IP PHONE	801 255-8899	Midvale	8:53 a.m.		2.0	-0.14
05/23	UT		IP PHONE	801 255-8899	Midvale	8:53 a.m.		2.0	-0.14
06/07	UT		IP PHONE	801 268-6900	Murray	9:31 a.m.		2.3	0.16
06/10	UT		IP PHONE	801 268-6900	Murray	9:30 a.m.		4.8	0.34
06/11	USA		IP PHONE	520 621-3232	Arizona	12:50 p.m.		2.2	0.20
Total for RHEES, R. WARD								3.3	0.28
Calls for: SEEGMILLER, ROBERT									
05/23	USA		IP PHONE	503 681-1142	Oregon	12:00 noon		1.4	-0.13
05/23	USA		IP PHONE	503 681-1142	Oregon	12:00 noon		1.4	-0.13
05/23	USA		IP PHONE	503 681-1142	Oregon	12:09 p.m.		4.2	-0.38

EXHIBIT E

CSU

July 2002

10th July - called Trent Lund ~ 2:15pm MT

- a. discussed EQUOR-DIT binding -
- b. racemic equal vs. R- & S-EQUOR
- c. can we get material from Ken?
- d. how much material is needed?

11th July called Trent Lund 4:20pm

- a. discussed to ^{work} forward with RvsS EQUOR binding -
- b. ENR to contact Ken - if he cannot provide equal material I have plenty of racemic equal

15th July called Trent - 3:40pm MT

- a. talked about - m/papers & other research projects involving phytoestrogens/ equal, etc.
- b. Can CSU chemistry dept - isolate R- & S-equal from racemic equal?
- c. to follow up - equal abstract for SFN send to Bob for review

EXHIBIT F

Billing Detail for Billable Calls

Date Type Proj From Number From Location To Number To Location Time Duration Amount

Account: 11223500-6140-00000 (Cont.)

Calls for: EVANS, R. PAUL (Cont.)

07/11	USA		IP PHONE	401 454-6661	Rhode Island	2:16 p.m.	0.4	0.04
07/11	USA		IP PHONE	401 454-6300	Rhode Island	2:23 p.m.	4.4	0.40
07/12	USA		IP PHONE	401 454-6661	Rhode Island	11:44 a.m.	0.3	0.03
07/12	UT	2-0519	WIDB 773	801 521-6280	Salt Lake Cit	2:20 p.m.	11.2	0.78
07/14	USA		IP PHONE	401 272-2400	Rhode Island	8:04 p.m.	1.1	0.10
07/14	USA		IP PHONE	401 272-1191	Rhode Island	8:05 p.m.	0.7	0.06
07/15	USA		IP PHONE	401 454-6661	Rhode Island	7:33 a.m.	2.1	0.19
07/15	USA		IP PHONE	401 454-6430	Rhode Island	10:34 a.m.	0.8	0.07
07/15	USA		IP PHONE	401 454-6625	Rhode Island	10:35 a.m.	2.2	0.20
07/16	USA		IP PHONE	978 927-5054	Massachusetts	12:24 p.m.	4.3	0.39
07/16	USA		IP PHONE	719 227-5202	Colorado	1:17 p.m.	1.7	0.15
07/16	USA		IP PHONE	401 454-6625	Rhode Island	2:33 p.m.	9.1	0.82
07/17	USA		IP PHONE	301 319-9853	Maryland	7:47 a.m.	1.3	0.12
07/17	USA		IP PHONE	301 662-6431	Maryland	7:49 a.m.	2.9	0.26
07/17	USA		IP PHONE	703 257-0214	Virginia	1:48 p.m.	0.4	0.04
07/18	USA		IP PHONE	401 272-5577	Rhode Island	2:48 p.m.	1.8	0.16
07/22	UT	2-0519	WIDB 773	801 364-9127	Salt Lake Cit	3:56 p.m.	0.9	0.06
07/22	UT	2-0519	WIDB 773	801 364-9127	Salt Lake Cit	3:59 p.m.	0.6	0.04
07/22	UT	2-0519	WIDB 773	801 364-9127	Salt Lake Cit	4:04 p.m.	1.6	0.11
07/22	UT	2-0700	WIDB 5748	801 364-9127	Salt Lake Cit	4:09 p.m.	0.7	0.05
07/25	USA		IP PHONE	617 496-3748	Massachusetts	3:01 p.m.	5.3	0.48
07/26	UT		IP PHONE	801 536-8817	Salt Lake Cit	9:14 a.m.	0.3	0.02

Total for EVANS, R. PAUL

73.0 6.72

Calls for: JUDD, ALLAN M.

07/11	USA		IP PHONE	435 797-1189	Logan	2:32 p.m.	1.0	0.09
07/11	USA	2-0700	WIDB 5748	435 797-1192	Logan	3:01 p.m.	2.5	0.23

Total for JUDD, ALLAN M.

3.5 0.32

Calls for: LEPHART, EDWIN D.

07/03	USA		IP PHONE	202 466-1050	Dist. of Colu	11:34 a.m.	5.0	0.45
07/05	USA		IP PHONE	310 206-2162	California	11:52 a.m.	0.3	0.03
07/08	USA		IP PHONE	970 491-5638	Colorado	12:12 p.m.	1.1	0.10
07/08	USA		IP PHONE	765 966-1885	Indiana	12:33 p.m.	7.3	0.66
07/08	USA		IP PHONE	202 328-7744	Dist. of Colu	12:42 p.m.	1.9	0.17
07/08	UT		IP PHONE	801 581-6287	Salt Lake Cit	12:54 p.m.	10.6	0.74
07/10	USA		IP PHONE	970 491-5638	Colorado	2:17 p.m.	37.2	3.35
07/11	USA		IP PHONE	970 491-5638	Colorado	4:24 p.m.	2.9	0.26
07/15	USA		IP PHONE	970 491-5638	Colorado	3:41 p.m.	20.0	1.80
07/16	USA		IP PHONE	513 636-4548	Ohio	8:52 a.m.	0.2	0.02
07/16	USA		IP PHONE	513 636-4548	Ohio	2:53 p.m.	4.7	0.42
07/17	USA		IP PHONE	970 491-5638	Colorado	12:12 p.m.	1.1	0.10
07/17	USA		IP PHONE	818 883-7043	California	11:46 a.m.	7.4	0.67
07/18	USA		IP PHONE	212 286-5575	New York	10:42 a.m.	25.8	2.32
07/19	USA	2-0601	WIDB 633	610 293-9299	Pennsylvania	8:49 a.m.	1.8	0.16
07/25	USA	2-0601	WIDB 633	202 462-1547	Dist. of Colu	3:34 p.m.	0.5	0.05
07/30	USA		IP PHONE	970 491-7130	Colorado	2:35 p.m.	22.8	2.05 B.H.

EXHIBIT G

Setchell
discussed

Wed 17th July 02 8:30AM MT

a. J Nutr - Equol review - Ken will send me a copy

b. Equol producers - human study ~ 20-30% population
lipid - cholesterol effects, ↓ LDL etc.

study - Australian group - Meyer B?

c. Soy Alzheimer's disease - work of Tom Clarkson?
Wake Forrest

d. Equol - provisional patent
Setchell involvement

a. intellectual

b. consult - participation thus far

c. studies to perform - DHT-Equol binding
HPLC

ii Not enough material for NMR

iii DHT-Equol binding
MS-SPC?

iv binding racemic equal to DHT
may be trapped between
R & S isomers

v. Estrogenic characteristic equal
R-Equol - bioactive?
S-Equol - bioactive/inactive for
binding DHT & estrogenic
properties

prostate
cancer?
Setchell - equal patent
Novel synthesis →
food applications

e. Discussed - inventorship - CSU, BYU - & Setchell
include Children's?, consider equally
as inventors

- equal synthesis/isolation R-Equol
S-Equol

EXHIBIT H

Billing Detail for Billable Calls

Date	Type	Proj	From Number	From Location	To Number	To Location	Time	Duration	Amount
Account: 11223500-6140-00000 (Cont.)									
Calls for: EVANS, R. PAUL (Cont.)									
07/11	USA			IP PHONE	401 454-6661	Rhode Island	2:16 p.m.	0.4	0.04
07/11	USA			IP PHONE	401 454-6300	Rhode Island	2:23 p.m.	4.4	0.40
07/12	USA			IP PHONE	401 454-6661	Rhode Island	11:44 a.m.	0.3	0.03
07/12	UT		2-0519	WIDB 773	801 521-6280	Salt Lake Cit	2:20 p.m.	11.2	0.78
07/14	USA			IP PHONE	401 272-2400	Rhode Island	8:04 p.m.	1.1	0.10
07/14	USA			IP PHONE	401 272-1191	Rhode Island	8:05 p.m.	0.7	0.06
07/15	USA			IP PHONE	401 454-6661	Rhode Island	7:33 a.m.	2.1	0.19
07/15	USA			IP PHONE	401 454-6430	Rhode Island	10:34 a.m.	0.8	0.07
07/15	USA			IP PHONE	401 454-6625	Rhode Island	10:35 a.m.	2.2	0.20
07/16	USA			IP PHONE	978 927-5054	Massachusetts	12:24 p.m.	4.3	0.39
07/16	USA			IP PHONE	719 227-5202	Colorado	1:17 p.m.	1.7	0.15
07/16	USA			IP PHONE	401 454-6625	Rhode Island	2:33 p.m.	9.1	0.82
07/17	USA			IP PHONE	301 319-9853	Maryland	7:47 a.m.	1.3	0.12
07/17	USA			IP PHONE	301 662-6431	Maryland	7:49 a.m.	2.9	0.26
07/17	USA			IP PHONE	703 257-0214	Virginia	1:48 p.m.	0.4	0.04
07/18	USA			IP PHONE	401 272-5577	Rhode Island	2:48 p.m.	1.8	0.16
07/22	UT		2-0519	WIDB 773	801 364-9127	Salt Lake Cit	3:56 p.m.	0.9	0.06
07/22	UT		2-0519	WIDB 773	801 364-9127	Salt Lake Cit	3:59 p.m.	0.6	0.04
07/22	UT		2-0519	WIDB 773	801 364-9127	Salt Lake Cit	4:04 p.m.	1.6	0.11
07/22	UT		2-0700	WIDB 5748	801 364-9127	Salt Lake Cit	4:09 p.m.	0.7	0.05
07/25	USA			IP PHONE	617 496-3748	Massachusetts	3:01 p.m.	5.3	0.48
07/26	UT			IP PHONE	801 536-8817	Salt Lake Cit	9:14 a.m.	0.3	0.02
Total for EVANS, R. PAUL								73.0	6.72
Calls for: JUDD, ALLAN M.									
07/11	USA			IP PHONE	435 797-1189	Logan	2:32 p.m.	1.0	0.09
07/11	USA		2-0700	WIDB 5748	435 797-1192	Logan	3:01 p.m.	2.5	0.23
Total for JUDD, ALLAN M.								3.5	0.32
Calls for: LEPHART, EDWIN D.									
07/03	USA			IP PHONE	202 466-1050	Dist. of Colu	11:34 a.m.	5.0	0.45
07/05	USA			IP PHONE	310 206-2162	California	11:52 a.m.	0.3	0.03
07/08	USA			IP PHONE	970 491-5638	Colorado	12:12 p.m.	1.1	0.10
07/08	USA			IP PHONE	765 966-1885	Indiana	12:33 p.m.	7.3	0.66
07/08	USA			IP PHONE	202 328-7744	Dist. of Colu	12:42 p.m.	1.9	0.17
07/08	UT			IP PHONE	801 581-6287	Salt Lake Cit	12:54 p.m.	10.6	0.74
07/10	USA			IP PHONE	970 491-5638	Colorado	2:17 p.m.	37.2	3.35
07/11	USA			IP PHONE	970 491-5638	Colorado	4:24 p.m.	2.9	0.26
07/15	USA			IP PHONE	970 491-5638	Colorado	3:41 p.m.	20.0	1.80
07/16	USA			IP PHONE	513 636-4548	Ohio	8:52 a.m.	0.2	0.02
07/16	USA			IP PHONE	513 636-4548	Ohio	2:53 p.m.	4.7	0.42
07/17	USA			IP PHONE	970 491-5638	Colorado	2:17 p.m.	37.2	3.35
07/17	USA			IP PHONE	818 883-7043	California	11:46 a.m.	7.4	0.67
07/18	USA			IP PHONE	212 286-5575	New York	10:42 a.m.	25.8	2.32
07/19	USA		2-0601	WIDB 633	610 293-9299	Pennsylvania	8:49 a.m.	1.8	0.16
07/25	USA		2-0601	WIDB 633	202 462-1547	Dist. of Colu	3:34 p.m.	0.5	0.05
07/30	USA			IP PHONE	970 491-7130	Colorado	2:35 p.m.	22.8	2.05 B.H.

EXHIBIT I

Subject: Equol-Lephart

Date: Fri, 07 Jun 2002 13:30:21 -0600

From: Edwin Lephart <Edwin_Lephart@byu.edu>

To: KSetchell@aol.com

CONFIDENTIAL- FOR KEN SETCHELL'S READING - ONLY

Hi Ken-

I have tried to call you a few times, but have missed you. Sorry our schedules have not matched up. I understand you are off to Australia for a few weeks, hope you are planning on enjoying yourself. [My email has been acting strangely this morning, so I hope this email goes through].

I would have preferred to visit with you over the telephone, but this will have to do for now. We have run several experiments on equol (binding and in vivo studies) and the data sets appear to be clear that equol is binding DHT specifically and not other androgens- like testosterone or androstenedione. Also, equol binds DHT in vivo and blocks the effects of DHT on LH levels and blocks the effects of DHT on the stress response (for stress hormones). Finally, in running column chromatography experiments, equol binds DHT, but does not displace DHT from the androgen receptor. Therefore, equol is acting as a specific DHT-antiandrogen without binding or altering the DHT-androgen receptor complex. Almost all of these studies have been performed at Colorado State by a former graduate student of mine. I have visited with my associates at CSU and we feel based upon the clear cut data sets we have obtained that the next natural step is to discuss with my office here at BYU to pursue a possible patent for the application of equol's characteristics as a specific DHT-antiandrogen. There certainly is a lot to visit with you about concerning our data sets, etc., however, I am writing this email to determine if you wish to be consider in the patent application/process?

I HAVE BEEN ADVISED BY THE PATENT OFFICE HERE AT BYU THAT WE (THE INVESTIGATOR'S) NOT DISCUSS THIS RESEARCH TOPIC WITH ANYONE, UNTIL THE PATENT PROCESS IS WELL UNDERWAY AND ONLY WITH SIGNED NON-DISCLOSURE STATEMENTS).

I know you are very busy, let me know what you think about this matter and if you happen to know the percentage of patent royalties (university vs. investigator) at Cinn, please also let me know this.

We feel these are very exciting findings with broad biomedical applications.

I look forward to hearing from you and hope you have a great trip.

Sincerely,

Eddie Lephart